REMARKS

Claim Amendments

Claim 1 has been amended to recite that the composition comprises about 0.1 μg to about 1000 μg of the HIV envelope antigen. Support for this amendment can be found in the specification, for example, at page 22, lines 9-11.

Support for new claims 30-33 and 35-38 can be found in the specification, for example, at page 22, lines 9-12 and Table 1 at page 25.

Support for new claim 34 can be found in the specification, for example, at page 8, lines 16-19.

Amendment of claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants reserve the right to file one or more continuing applications hereof.

Restriction Requirement

Applicants affirm the election with traverse of Group 1, which corresponds to claims 1, 2 and 4-16 drawn to compositions comprising HIV envelope antigens and LTK63. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the non-elected inventions. Applicants do not hereby abandon or waive any rights in the non-elected inventions. The requirement is being traversed for the reasons set forth in detail below.

In accordance with the Office's grouping of the claims, it is believed that new claims 30-34 fall in Groups 1 and 2, new claim 35 falls in Groups 3 and 4, new claim 36 falls in Groups 5 and 6, new claim 37 falls in Groups 9 and 10 and new claim 38 falls in Groups 11 and 12.

The Office states that the inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. More specifically, the Office urges that the technical feature of the invention LTK63 is known in the art and thus, "cannot be said to be a special technical feature" (Office Action at page 3). In support, the Office cites Partidos et al.

(Immunology 89:483-487 (1996)) and Vajdy et al. (7th Conference on Retroviruses and Opportunistic Infections (2000)).

Applicants respectfully disagree that Groups 1, 3, 5, 7, 9 and 11 do not relate to a single general inventive concept, and that Groups 2, 4, 6, 8, 10 and 12 do not relate to a single general inventive concept.

According to PCT Rule 13.1, the subject application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. See also 37 C.F.R. § 1.475(a). PCT Rule 13.2 provides that where a group of inventions is claimed in an application, the requirement of unity of invention is fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. See also 37 C.F.R. § 1.475(a). The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the specification.

The special technical feature common to each of Groups 1, 3, 5, 7, 9 and 11 is a composition comprising an HIV envelope antigen and LTK63, wherein the HIV envelope antigen is in an amount of about 0.1 μg to about 1000 μg. The special technical feature common to each of Groups 2, 4, 6, 8, 10 and 12 is a composition comprising an HIV envelope antigen and LTR72.

Partidos et al. disclose intranasal immunization of mice with a measles virus peptide and LTK63. However, Partidos et al. do not teach or suggest any composition comprising an HIV envelope antigen. Partidos et al. also do not teach or suggest any compositions comprising LTR72.

Vajdy et al. disclose intranasal immunization of mice with an HIV envelope protein and LTK63. However, Vajdy et al. do not specify any particular amounts for the HIV envelope protein. Vajdy et al. also do not teach or suggest any composition comprising LTR72.

Thus, neither Partidos et al. nor Vajdy et al. teach or suggest a composition comprising an HIV envelope antigen and LTK63, wherein the HIV envelope antigen is in an amount of about 0.1 μg to about 1000 μg (the special technical feature common to each of Groups 1, 3, 5, 7, 9 and

11). Accordingly, the inventions listed as Groups 1, 3, 5, 7, 9 and 11 relate to a single general inventive concept. Therefore, unity of invention exists between Groups 1, 3, 5, 7, 9 and 11.

Similarly, Partidos et al. and Vajdy et al. do not teach or suggest a composition comprising an HIV envelope antigen and LTR72 (the special technical feature of Groups 2, 4, 6, 8, 10 and 12). Accordingly, the inventions listed as Groups 2, 4, 6, 8, 10 and 12 relate to a single general inventive concept, and unity of invention exists between these Groups.

It is noted that the above analysis is in accord with the International Preliminary Examination Report (IPER) dated June 10, 2004, where the IPEA considered that claims 1-16 related to two general inventive concepts under PCT Rule 13.1. More specifically, the IPEA considered Group I (claims 1-16, in part) as drawn to a composition comprising an HIV envelope antigen and LTK63, and Group II (claims 1-16, in part) as drawn to a composition comprising an HIV envelope antigen and LTR72.

Applicants also submit that the examination of Groups 1, 3, 5, 7, 9 and 11 together would not place an undue burden upon the Office. A search of the prior art for the compositions or methods defined in one group would also identify prior art that is applicable to the compositions and methods defined by the other groups. Furthermore, a complete search of the invention of one group would necessarily entail a search of the invention of the other groups. Thus, no excessive searching burden would be placed upon the Office in examining Groups 1, 3, 5, 7, 9 and 11 together.

Similarly, Applicants submit that the examination of Groups 2, 4, 6, 8, 10 and 12 together would not place an undue burden upon the Office. A search of the prior art for the compositions or methods defined in one group would also identify prior art that is applicable to the compositions and methods defined by the other groups. Furthermore, a complete search of the invention of one group would necessarily entail a search of the invention of the other groups. Thus, no excessive searching burden would be placed upon the Office in examining Groups 2, 4, 6, 8, 10 and 12 together.

For the foregoing reasons, withdrawal of the finding that Groups 1, 3, 5, 7, 9 and 11 do not have unity of invention is respectfully requested. Withdrawal of the finding that Groups 2, 4, 6, 8, 10 and 12 do not have unity of invention is also requested.

Rejoinder

Notwithstanding the above, Applicants request that claims 19-27, drawn to methods of using the compositions of Group 1, be rejoined per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Title of the Invention

The Title of the Invention has been objected to as not descriptive.

In response to this objection, the title has been amended to HIV VACCINE FOR MUCOSAL DELIVERY. It is believed that this title is more clearly indicative of the invention to which the claims are directed.

Rejection Under 35 U.S.C. § 102

Claims 1, 2, 4-6 and 14-16 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Vajdy et al. (7th Conf. on Retroviruses and Opportunistic Infections, 2000). This rejection is respectfully traversed.

As amended, claims 1, 2, 4-6 and 14-16 recite a composition that comprises an HIV envelope antigen in an amount of about 0.1 μg to about 1000 μg and LTK63 or LTR72.

Vajdy et al. is an abstract that discloses intranasal immunization of mice with HIV envelope antigens and an LTK63 adjuvant. Importantly, Vajdy et al. do not teach or suggest any particular amounts for the HIV envelope antigen. Vajdy et al. also do not teach or suggest any composition comprising LTR72. Thus, the composition of claims 1, 2, 4-6 and 14-16, as amended, differs from the composition disclosed by Vajdy et al. in the amount of the HIV envelope antigen component. In other aspects, the composition of claims 1, 2, 4-6 and 14-16, as amended, differs from the composition disclosed by Vajdy et al. in the presence of an LTR72 adjuvant. Therefore, claims 1, 2, 4-6 and 14-16, as amended, are not anticipated by Vajdy et al.

Reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b) are respectfully requested.

Rejection of Claims 1, 2, 4-10 and 13-16 Under 35 U.S.C. § 103

Claims 1, 2, 4-10 and 13-16 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the reference of Vajdy et al. (*supra*). This rejection is respectfully traversed.

Claims 1, 2, 4-10 and 13-16 relate to a composition comprising an HIV envelope antigen in an amount of about 0.1 μg to about 1000 μg and LTK63 or LTR72.

Vajdy et al. teach intranasal immunization of mice with an HIV envelope protein and an LTK63 adjuvant. Vajdy et al. also teach intranasal and oral immunization of mice with an HIV gag protein and LTK63. Importantly, as discussed above, Vajdy et al. do not teach or suggest any particular amounts for the HIV envelope protein. Vajdy et al. also do not teach or suggest any composition comprising LTR72. Accordingly, Vajdy et al. would not have suggested the claimed invention to one of ordinary skill in the art. In fact, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness.

Reconsideration and withdrawal of this rejection of claims 1, 2, 4-10 and 13-16 under 35 U.S.C. § 103(a) are respectfully requested.

Rejection of Claims 1, 11 and 12 Under 35 U.S.C. § 103

Claims 1, 11 and 12 have also been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Vajdy et al. (supra) in view of Spalding (Bio/Technology 10:24-29 (1992)). Applicants respectfully traverse this rejection.

Vajdy et al. is discussed in detail above. Notably, Vajdy et al. do not teach or suggest any particular amounts for the HIV envelope protein component of the claimed composition. Vajdy et al. also do not teach or suggest any composition comprising LTR72.

Spalding does not cure the deficiencies of the Vajdy et al. reference. Spalding is a 1992 general review article listing several HIV vaccine candidates in development as of 1992. Although, as noted by the Examiner in the Office action, Tat and Vpu proteins are listed in a table in the reference, Spalding does not specifically teach or suggest any HIV vaccine

candidates including a Tat or Vpu protein. Importantly, Spalding does not teach or suggest any HIV vaccine candidates comprising any particular amounts of an HIV envelope antigen or comprising a mucosal adjuvant such as LTK63 or LTR72.

The Office urges that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to combine one or more of the known antigens with the LTK63 mucosal adjuvant", and one would have been motivated to do so "for the advantages taught by Vajdy et al. such as inducing a systemic as well as mucosal immune response which would protect mucosa at the site of viral entry" (Office Action at page 7). However, this is not a motivation to combine references or known antigens with LTK63, but rather is the conclusion the Office has apparently reached after having benefited from reading Applicants' own disclosure, and thus is impermissible hindsight.

Evening assuming *arguendo* that the Office has properly combined Vajdy et al. and Spalding, this proposed combination of references would not have suggested to one of ordinary skill in the art, at the time the invention was made, Applicants' claimed composition comprising an HIV envelope antigen in an amount of about 0.1 μg to about 1000 μg and LTK63 or LTR72, particularly since neither Vajdy et al. nor Spalding teach or suggest use of any particular amounts for an HIV envelope antigen in an HIV vaccine. Thus, as above, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness.

Reconsideration and withdrawal of this rejection of claims 1, 11 and 12 under 35 U.S.C. § 103(a) are respectfully requested.

CONCLUSION

In light of the above remarks and amendments, Applicants submit that the present application is in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates another action, or if a telephone conference would expedite allowance of the claims, the Examiner is invited to contact the undersigned.

The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

Please direct all further written communications regarding this application to:

Helen Lee
Chiron Corporation
Intellectual Property - R440
P. O. Box 8097
Emeryville, CA 94662-8097
Tel: (510) 923-2192
Fax: (510) 655-3542

Respectfully submitted,

Date: March 6, 2006

By: Jenny Buchbinder

Jenny Buchbinder, Ph.D.
Registration No. 48,588
(650) 354-3383

CHIRON CORPORATION
Intellectual Property - R440
P. O. Box 8097
Emeryville, CA 94662-8097